REMARKS

1. In response to the Office Action mailed December 30, 2010, Applicants respectfully request reconsideration. Claims 54, 56-75, 77-81 and 83-85 were last presented for examination. Of these claims 54, 56-69 are withdrawn. In the outstanding Office Action, claims 70-75, 77-81 and 83-85 were rejected. By this paper, no claims are amended, canceled or added. Upon entry of this paper, claims 54, 56-75, 77-81 and 83-85 will be pending in this application. Of these twenty-nine (29) claims, three (3) claims (claims 54, 70 and 84) are independent.

2. Based upon the following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Rejections under 35 U.S.C. 112, first paragraph

3. The Office Action rejects claims 84 and 85 under 35. U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants traverse these rejections for the reasons that follow.

4. Applicants respectfully traverse this ground for rejection. Applicants rely on MPEP §2106(V)(B), entitled "Determining Whether the Claimed Invention Complies with 35 U.S.C. §112, First Paragraph Requirements," subsection 1, which states, immediately after discussing the "reasonable conveyance" requirement (see Office Action) that the "claimed invention subject matter *need not be described literally*, i.e., *using the same terms*, in order for the disclosure to satisfy the description requirement." (Emphasis added) Applicants respectfully submit that the claims of the present invention find sufficient written description in the as-filed specification, as will now be detailed.

5. The Office Action rejects claim 84 on the grounds that "the examiner was unable to find written description support . . . for a collar having a 'non-porous cavity'. . . or an outlet that 'faces the electrode assembly.'" (Office Action, page 2.)

6. Figure 20 of Applicants' application, reproduced below, depicts element 246 and element 232. Applicants' specification identifies element 246 as an "outlet."

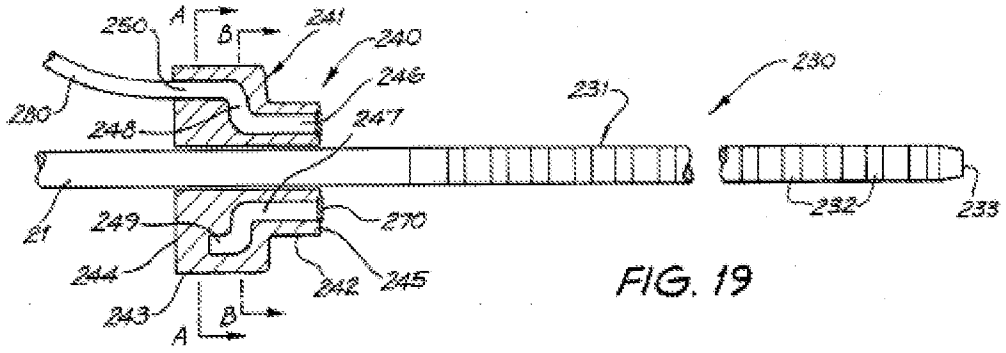

FIG. 19

The specification further states that an "embodiment . . . of a hearing implant *electrode assembly* . . . is depicted generally as 230." (Page 30, lines 24-26, emphasis added.) FIG. 19 shows reference number 230 coupled with an arrow pointing to a location that is faced by the outlet 246. Thus, there is written description support for an outlet that faces an electrode assembly for at least this reason, but there is more. The specification goes on to state that the "assembly 230 includes an elongate member 231 that has a distal end 233 that is firstly inserted into the cochlea." (Page 30, lines 28-29.) The "assembly 230" just referred to is the "electrode assembly" 230 previously disclosed. Because the specification teaches that the electrode assembly 230 includes an elongate member 231, and because FIG. 19 clearly shows the outlet 246 facing the elongate member 231, FIG. 19 depicts outlet 246 facing an electrode assembly.

7. With regard to the recitation of claim 84 that the collar has a "non-porous cavity," applicants submit that the person of ordinary skill in the art would have recognized that Applicants' disclosed this feature based on FIG. 19, especially when compared with prior teachings in the application. Specifically, Applicants' application initially states that "FIGS. 6a and 6b depict a surface of an elongate member 71 that is surrounded by a sheath 72 fabricated from a porous material." (Emphasis added.) FIGs. 6a and 6B are reproduced below.

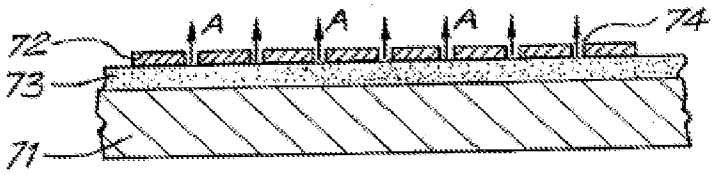

FIG. 6a

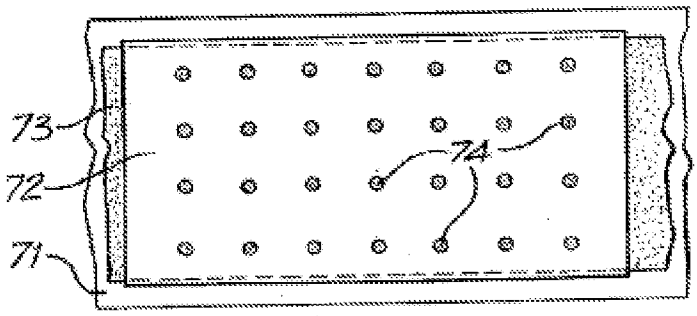

FIG. 6b

8. As may be seen in FIG. 6a, Applicants' show a cross-sectional view having pores 74 to depict a porous body. In contrast, the cross-sectional view of FIG. 19 shows no such pores bounding chamber 247. Instead, the cross-hatching is solid. It is not interrupted by pores like those shown in FIG. 6a. Thus, the person of skill in the art would have recognized that Applicants' disclosed a cavity that is non-porous at the time they filed their application. Reconsideration and withdrawal of the written description rejection of claim 84 is requested.

9. The Office Action rejects claim 85 on the grounds that "while the examiner was able to find support for a semi-permeable membrane that can act as a valve means . . . the examiner was unable to find support for an outlet comprise a valve . . . the scope of 'a valve' would include actual mechanical valve elements (like flap valves), but the disclosure only appears to support a semi-permeable membrane that 'can act as a valve means." Applicants traverse this erroneous interpretation of the written description requirement.

10. Applicants disclose that the "membrane 270 can act as a valve means that allows fluid to exit the chamber but prevents, or at least substantially prevents, fluid flow from external the chamber back into the chamber within the body." (Emphasis added.) That is, Applicants disclose a species (the membrane 270) of a genus (the valve means). There is no requirement pertaining to the number of disclosed embodiments of given feature, at least in the mechanical arts, that an applicant must meet to establish written description support for a claim element. Regardless, Applicants disclose a valve means that allows fluid to exit the chamber but prevents the reverse. The person of skill in the art would thus have recognized that Applicants disclosed "a valve configured to allow the bioactive substance contained in the cavity to exit the cavity and at least substantially prevent fluid flow from external the cavity into the cavity." (Claim 85.) Reconsideration and withdrawal of the written description rejection of claim 85 is requested.

Rejections assumed arguendo under 35 U.S.C. 112, second paragraph

11. The Office Action recites language from 35. U.S.C. 112, second paragraph, and then goes on to state that the "written description fails to clearly link or associate the disclose structure" to the recited "slider means for delivery of a bioactive substance." Presumably, the Office Action intended to reject claim 70 and its dependencies under 35. U.S.C. 112, second paragraph, even though the Office Action never does so. Applicants take this opportunity to detail why claim 70 and its dependencies should not be rejected under 35 U.S.C. 112, second paragraph, in any future rejection.

12. MPEP §2181(III), entitled "Determining 35 U.S.C. 112 Second Paragraph Compliance When 35 U.S.C. 112 Sixth Paragraph is Invoked," states that the

> following guidance is provided to determine whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph, when 35 U.S.C. 112, sixth paragraph, is invoked:
>
> (A)If the corresponding structure, material or acts are described in the specification in specific terms (e.g., an emitter-coupled voltage comparator) and one skilled in the art could identify the structure, material or acts from that

> description, then the requirements of 35 U.S.C. 112, second and sixth paragraphs are satisfied.

(MPEP §2181(III).)

13. As may be seen from the just-quoted passage, there is no requirement for word-for-word "antecedent basis" in a specification with respect to means-plus-function claim recitations. The corresponding structure is described in the specification in specific terms that one skilled in the art can identify the structure from the description in the specification. Further, the rejections under 35 U.S.C. §112, second paragraph, are not consistent with proper PTO procedures. The meaning (or alleged lack of meaning) of a claim term / phrase is not measured by the perceptions of an individual examiner. Rather, the standard is that of the skilled artisan, informed by the disclosure and the prior art. (*See* MPEP §2173.02.) Specifically, MPEP §2173.02 states that definiteness of claim language ***must be analyzed, not in a vacuum***, but in light of:

> (A) The content of the particular application disclosure;
>
> (B) The teachings of the prior art; and
>
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

(MPEP §2173.02, emphasis added.)

14. The burden of providing proof supporting the rejection of a claim as indefinite is on the examiner. In the Office Action, the claims are sweepingly rejected simply because every "means for" recitation is not allegedly repeated or even identified in the specification. No other basis is provided for rejecting the claims under 35 U.S.C. §112, second paragraph. This does not satisfy the burden placed on an examiner when rejecting a claim as indefinite.

15. Moreover, the Office Action identifies a series of alternative requirements on page 4 that the Office Action and asserts that an Applicant must conform with at least one of them (while never citing a single statute, regulation, or even MPEP section in support of these alleged requirements), one of which is stating "on the record where the corresponding structure . . . are set forth in the written description of the specification that perform the claimed function. Without conceding the proprietary of these alleged requirements,

Applicants hereby state, on the record, that an example of a corresponding structure, material or act that performs the function of the slider means for delivery of a bioactive substance may be found on page 30, line 20 to page 31, line 26, and FIGs. 19, 19a and 19b. More specifically, collar 240 is an example of a slider means. No future rejection of the claims that recite slider means is requested.

Claim Rejections – 35 USC § 102 and § 103

16. Claims 70, 72-75, 78-81 and 83 are rejected under 35 U.S.C. 102(e) as being unpatentable over Kramm et al. (U.S. Patent No. 6,936,040, hereinafter "Kramm"). Further, claims 72 and 83-85 arte rejected under 35 U.S.C. 103 as being unpatentable over Kramm in view of Kuzma (U.S. Patent No. 6,309,410, hereinafter "Kuzma"). In response, Applicants traverse the rejections of these claims.

17. Claim 70 is written as a "means-plus-function" claim pursuant to 35 U.S.C. §112, sixth paragraph. It is respectfully submitted that the USPTO has not met its burden under the post-*Donaldson*[1] requirements to show that the alleged "slider means for delivery of a bioactive substance" of Kramm is the equivalent to the structure of the collar 240 of Fig. 19 of Applicants' specification (which corresponds to the recited slider means.

18. Specifically, the Office Action identifies an element in the prior art that allegedly performs the function specified in claim 70, but only relies on the alleged functionality of the element to support the allegation that the prior art element is an equivalent of the means-plus-function recitation of claim 70. The Office Action never analyzes the structure disclosed in Applicant's specification and never explains why that structure is an equivalent. Instead, there is only the allegation that equivalence exists because the prior art allegedly performs the same function. Put bluntly, the Office Action predicates its rejection of claim 70 based on pre-*Donaldson* standards of examining means-plus-function recitations. The Federal Circuit barred the USPTO from relying on such standards in 1994 in its *In Re*

[1] *In re Donaldson Co.*, 16 F.3d 1189 (Fed. Cir. 1994).

Donaldson case, and the MPEP makes clear that those standards are no longer acceptable for examining claims drafted pursuant to 35 U.S.C. 112, 6th paragraph.

19. In rejecting claim 40, the Office Action states that the "examiner is considering Kramm's element 48 and distal portions 42 and 56 to be equivalent to the claimed 'slider means' because it slides with respect to the lead and functions to deliver bioactive substances to a target site in a recipient." (Office Action, page 5, first paragraph.) That is, elements 48, 42 and 56 are considered to be an equivalent based solely on how those elements function. This is improper examining procedure, as the rejection comports with only the now barred pre-*Donaldson* interpretation of 35 U.S.C. 112, 6th paragraph, as will now be shown.

20. The MPEP states that when

> making a determination of patentability under 35 U.S.C. 102 or 103, past practice was to interpret a "means or step plus function" limitation by giving it the "broadest reasonable interpretation." Under the PTO's long-standing practice this **meant** interpreting such a limitation as reading on any prior art means or step which performed the function specified in the claim without regard for whether the prior art means or step was equivalent to the corresponding structure, material or acts described in the specification. However, in *Donaldson,* the Federal Circuit stated:
>
> > Per our holding, the "broadest reasonable interpretation" that an examiner may give means-plus-function language is that statutorily mandated in paragraph six. Accordingly, the PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination.

(MPEP 2181, 4th and 5th paragraph (page 2100-234). That is, the MPEP explicitly details its examining practice prior to *In Re Donaldson* as "interpreting such a limitation as reading on any prior art means or step which performed the function specified in the claim." (Emphasis added.)

21. MPEP 2182 goes on to further detail the differences between the pre-*Donaldson* standards and the current, post-*Donaldson* standards, detailing that once a prior art reference

is identified that teaches identity of function, the Examiner still carries the burden to show equivalence.

> Both before and after *Donaldson*, the application of a prior art reference to a means or step plus function limitation requires that the prior art element perform the identical function specified in the claim. However, if a prior art reference teaches identity of function to that specified in a claim, then under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function.

(MPEP 2182, third paragraph (page 2100-241).) That is, the MPEP details that under the post-*Donaldson* standard, even after a prior art reference is identified that teaches an element having the functionality of the recitation under examination, the "examiner still carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function." (Emphasis added.)

22. Applicants ask how the rejection of claim 70 proffered in the Office Action is different from the now forbidden pre-*Donaldson* USPTO practice outlined above? That is, the Office Action nowhere analyzes the structure disclosed in Applicants' specification that corresponds to the slider means, and only proffers an assertion of obviousness based on the alleged functionality of the prior art elements. The Office Action never attempts to show that the prior art structure of Kramm "is the same as or equivalent to the structure . . . described in the specification which has been identified as corresponding to the claimed means or step plus function." All that the Office Action does is identify the alleged corresponding structure and assert its equivalence based on functionality of that structure. While acceptable prior to 1994, this is no longer acceptable practice. Accordingly, a *prima facie* case of anticipation against claim 70 has not been established pursuant to the MPEP.

23. Claim 84 recites a cochlear implant comprising a "collar having a non-porous cavity therein configured to receive a bioactive substance and an outlet located on an exterior face of the collar through which the bioactive substance can pass from the cavity to a target site in the recipient, wherein the outlet faces the electrode assembly and forms a boundary of the cavity." (Claim 84, emphasis added.)

24. The Office Action asserts that Kramm discloses "an annular collar (elements 42, 48 and 56) *mounted on the lead* and having a non-porous cavity (lumen 56) therein and an outlet located on an exterior face of the collar . . . wherein the outlet faces the electrode assembly (the inner and distal surfaces of 48 face the electrode assembly in a radially-inward direction and in a distal direction)." (Office Action, pages 6-7, sentence spanning.) Applicants traverse this rejection.

25. First, claim 84 recites that the "collar [is] slidably mounted *around* the lead," not just "*on* the lead" as is asserted in the Office Action. (Claim 84 and Office Action pages 6-7, sentence spanning, emphasis added to both.) Element 56 is not an annular collar, nor is it slidably mounted around the lead. Instead, it is identified in Kramm as a "passageway" that extends along the length of tubular body 42. (Kramm, column 6, lines 40-45.)

26. Second, Kramm does not teach that passageway 56 forms a non-porous cavity *in* a collar (assumed arguendo to correspond to distribution device 48). Passageway 56 extends to distribution device 48, but there is no teaching in Kramm of the structure of passageway 56 or that the passageway forms any type of non-porous cavity therein. That is, there is no teaching in Kramm that the structure of passageway 56 is or is not porous. Indeed, there is no teaching of the structure at all, instead only a teaching its functionality and the depiction of passageway 56 in Kramm in Figure 6 of Kramm is identical to the depiction of distribution device 48, which is porous. Further, even if passageway 56 was non-porous, there is no teaching that the structure of passageway 56 actually extends into distribution device 48, as opposed to stopping at distribution device 48 and being connected to a chamber in distribution device 48.

27. Third, even if passageway 56 were to extend into the distribution device 48 and even if it was a non-porous structure, there still would not be a non-porous cavity in the distribution device 48. Claim 84 recites an outlet that faces an electrode assembly, wherein the outlet forms a boundary of the cavity. The only outlet of Kramm that can face the electrode assembly is an outlet that faces the distal direction (there is no outlet that faces radially inward, as that is bounded by lumen 42, and is thus not an outlet) – it is the distal direction towards which passageway 56 ends (assuming that it extends into distribution device 48). This "outlet" is bounded by distribution device 48. Kramm explicitly teaches that distribution device 48 is made of a porous material. (Kramm, column 6, lines 40-47.) Thus, any cavity in distribution device 48 through which vasodilating agents travel necessarily constitutes a porous cavity because the cavity is bounded by the porous material of the distribution device 48. That is, the outlet is part of the cavity, and the outlet is formed by porous material, and thus the cavity is a porous cavity.

28. Claim 85 recites that the "outlet comprises a valve configured to allow the bioactive substance contained in the cavity to exit the cavity and at least substantially prevent fluid flow from external the cavity into the cavity." (Claim 85.)

29. The Office Action asserts that "Kramm's semi-permeable distributor is necessarily capable of providing the claimed functional limitations due to the pressure differential required to deliver a bioactive substance (*i.e.,* to deliver the substance, the substance necessarily need to be flowing out and substantially preventing fluid from flowing in)." (Office Action, page 7, last paragraph.) By proffering the pressure differential, Office Action has essentially described an open hose, and asserted that an open hose is a valve. This is an impermissible evisceration of the claim terms of claim 85. Kramm does not teach or suggest a valve, and claim 85 is allowable for at least this reason.

30. Further, the Office Action bases its rejection based entirely on the alleged function of a valve. The "examiner is considering Kramm's semi-permeable distributor as necessarily capable of providing the claimed functional limitations." (Office Action, page 7, last paragraph.) It is not enough to reject a claim that recites a structural element based merely on alleged functionality. This is yet another example of an impermissible evisceration of the claim terms of claim 85.

31. Kramm fails to teach the features of claims 84 and claims 85. These claims are thus allowable for at least these reasons. Allowance is requested.

Dependent Claims

32. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

Conclusion

33. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

34. Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and reserves the right to purse such claims in a continuation or divisional application.

35. EXCEPT for the issue fees payable under 37 C.F.R. § 1.18, the Director is authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.1.6 and 1.17 that may be required, including any required extension of time fees, or credit any overpayment to Deposit Account Number 11-0855. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

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